

REMARKS

Claims 2-7 and 10 are in this application. Claim 11 has been cancelled. Claim 10 has been amended to read “Method of treating psoriasis wherein a pharmaceutical composition comprising pharmaceutically active amounts of a) L-amino acids serine and isoleucine, b) trace elements chromium, tin, selenium, vanadium, and wolfram, and c) folic acid are administered orally to a patient in need thereof.”

Claims 2, 3, 4, and 5 have been amended to change “a pharmaceutical” to “the pharmaceutical composition” based on the claim dependency on claim 10.

Claim 5 has been amended to include that the neurogenic lipids are obtained from pig brains. Support for this amendment is found on page 4, lines 8-10.

The Examiner has rejected claim 11 under 35 USC 112, first paragraph as failing to comply with the written description requirement. Claim 11 was also rejected under 35 USC 112, first paragraph as not being enabled. Applicants respectfully traverse these rejections and consider that this claim is fully supported in the specification, and complies with the written description and enablement requirements of 35 USC 112, first paragraph. However, to expedite prosecution of this application, claim 11 has been cancelled. It is respectfully requested that the rejections of Claim 11 under 35 USC 112, first paragraph be withdrawn.

All rights to file one or more divisional applications to the subject matter of claim 11 and any other subject matter disclosed in the application and not presently, claimed is preserved.

Claims 10-11 were rejected under 35 USC 112, second paragraph as being indefinite. In view of the amendment of claim 10 to include the phrase “a pharmaceutical composition comprising” and cancellation of claim 11, this rejection is moot. It is respectfully requested that this rejection be withdrawn.

Claims 2-7 were rejected under 35 USC 112 is being indefinite. In view of the

amendment of claims 2-5 and claim 10, this rejection is moot and it is respectfully requested that this rejection be withdrawn.

Claims 3-7 and 10 have been rejected under 35 USC 103(a) as being obvious over the combination of Tallberg, et al. in view of Bodaness. Applicants respectfully traverse this rejection.

Tallberg et al. teaches compositions comprising various amino acids and trace elements and that these compositions are useful in bio-immunotherapy. Bio-immunotherapy described in this reference is a biologic treatment using dietary supplements of various amino acids and trace elements and in addition, in some experiments cooked pig brain aimed at biochemical pathways particularly those of the mitochondria is used. As the Examiner noted, Tallberg does not teach the use of these compositions (or bio-immunotherapy in general) for psoriasis. As explained in the previous response the etiology and pathology of psoriasis is completely different from that of skin cancer. Left untreated many skin cancers will continue to grow and spread leading to the patient's death. This is not the case with psoriasis. There are no tumors, malignant growth or uncontrolled cell division.

There is no suggestion in Bodaness that the use of any amino acid and specifically serine and isoleucine and folic acid would have any place in the treatment of psoriasis. Bodaness is directed to the teaching of administering a peroxide reactive, metal ion containing compound which localizes the tissue to be destroyed after which a peroxide compound is administered which reacts with the metal ion containing compound and forms a product (an oxidant). The formed oxidant is in turn capable of destroying tissue and can be used for treating diseases characterized by accumulation of cells. See column 4, lines 44-46.

In column 7, lines 32 to 55 the function of the metal in the "metal-ion containing compound" is explained as any metal, which is peroxide reacting. In other words, the metal reacts with the peroxide, for example H_2O_2 , and forms oxidant species such as OH^\cdot radicals. The oxidant species in turn destroy the tissue. The function of the metal-ion is not to treat the

illness. Bodaness teaches that certain metal-ions are peroxide reactive and that oxidant species can destroy tissue.

Examples described in column 4 of Bodaness are metal-porphyrin compound or a metal-porphyrin-antibody compound. Bodaness describes in column 5, the reaction product of the chemical reaction between the peroxide and the tumor-localized metal-ion containing compound is an oxidant species which destroys the cancer.

As explained in the previous response, the Examiner has relied on impermissible hindsight in making this rejection. Given the differences between the prior art, the claims at issue and the level of ordinary skill in the pertinent art, it would not be obvious to administer orally a composition that comprises serine, isoleucine, chromium, tin, selenium, vanadium, wolfram and folic acid to treat psoriasis.

A person skilled in the art setting out to develop a new treatment for psoriasis would have to not only realize that bio-immunotherapy (which previously have been suggested only as a treatment for certain cancers) can be used for psoriasis, but also to find the claimed combination of amino acids and trace-elements are effective to treat psoriasis. Although Bodaness mentions oral administration, the treatment described in the reference is topical. Neither the illness (psoriasis) nor the composition disclosed or suggested in claim 10 is disclosed in Tallberg et al and Bodaness et al alone or in combination. Applicants disagree with comments made by the Examiner in the Advisory Action.

According to the U.S. Supreme Court in KSR v. Teleflex as included in the Examination Guidelines for Determining Obviousness Under 35 USC 103 “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” Since this has not been shown, it is respectfully requested that the rejection be withdrawn.

There is no suggestion in the combination of references cited of the claimed method of treatment of psoriasis.

As argued previously, one skilled in the art would not have a reasonable expectation of success of combining the disclosures of Tallberg and Bodaness for treating psoriasis. Bodaness discloses a two-step treatment consisting of a cancer localizing peroxide-reactive metal-ion containing compound and then administering a peroxide compound. Bodaness teaches that both of these steps required. There is no suggestion or reasonable expectation of success that selecting a particular metal ion will be sufficient to treat psoriasis. The disclosure in col. 7, lines 33-40 is to be read in context which is that the metal ions are not used alone but are used in peroxide reactive metal-ion containing tumor localizing compound as described in lines 4-14 of column 7. The discussion in column 16, lines 3-15 states that metal-free organic compounds can be used. The listing of metals in line 3 of column 16 does not state that these metals can be used to treat psoriasis. Furthermore, there is no reason that one of skill in the art would combine Bodaness with Tallberg. While Bodaness refers to psoriasis there is no reference to this in Tallberg. In addition, as stated above, Bodaness teaches a two step process for treating cancer and psoriasis and there is no reason that one of skill in the art would select an element from that reference and combine it with a reference that teaches treatment of an entirely different disease.

Therefore, current claim 10 is non-obvious over the cited prior art and the Applicant kindly requests that the rejection be withdrawn.

Claim 2 is rejected under 35 USC 103(a) as being unpatentable over Tallberg et al. in view of Bodaness as applied to claims 3-7 and 10 above further in view of Yoneda et al (U.S. Patent 5,997,852).

Tallberg and Bodaness were discussed above.

The combination of these two references with Yoneda also does not make the claims obvious. Yoneda discloses zinc in combination with at least one compound selected from the group consisting of multivalent unsaturated fatty acids and their esters. Although reference is made to minerals and amino acids in column 3, the multivalent unsaturated fatty acids and their

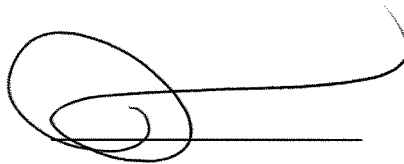
esters are required. Therefore, one of skill in the art would not arbitrarily pick zinc out of this reference.

It is respectfully requested that this rejection be withdrawn.

The term "neurogenic lipids" is still being rejected by the Examiner as indefinite. The Examiner states that the term seems to define the origin of the lipids and not what the lipids are. Claim 5 has been amended to define that the neurogenic lipids are obtained from pig brains. Support for this amendment is found on page 4, first full paragraph. A copy of the Tallberg, et al. article (Tallberg T. et al. Cancer Immunity. The Effect in Cancer-Immunotherapy of Polymerised Autologous Tumour Tissue and Supportive Measures. Scand. J. Lab. Invest. 1979:39 p. 3-33) is attached. Therefore, it is respectfully requested that the rejection be withdrawn.

Accordingly, it is submitted that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, consisting of a large, stylized loop followed by a horizontal line extending to the right.

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